K 103032

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05 510(k) Summary

JAN 14 2011

Applicant:	Olympus Winter & Ibe Kuehnstr. 61 22045 Hamburg Germany Tel.: +49-40-66966-0 Fax: +49-40-66966-2109 Establishment Registration Number: 9610773
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Manufacturer:	Olympus Winter & Ibe Kuehnstr. 61 22045 Hamburg Germany Tel.: +49-40-66966-0 Fax: +49-40-66966-2109 Establishment Registration Number: 9610773
Date Prepared:	August 9, 2010
Trade Name:	ESG-400
Common Name:	Electrosurgical Unit (ESU)

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Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulation No:	878.4400
Product Code:	GEI
Device Class:	II

Legally Marketed Predicate Devices:

Trade Name	510(k)	Applicant
Erbe VIO ESU (Model VIO 300 D) with Accessories	K023886	Erbe USA, Inc.
Erbe VIO ESU (Model VIO 300 D)	K060484	Erbe USA, Inc.
XUES-41	K030194	Olympus Optical Co.Ltd.

Device Description:

The ESG-400 is a reusable, non-sterile electrosurgical generator that features different mono- and bipolar cutting and coagulation modes. The maximum output power is 320 W.

On the front side it features a touch screen display that displays the connection status of accessories and peripherals connected to the electrosurgical generator. It is also used to show and modify the output settings (e.g. mode, output power, effect) as well as to control other functions (e.g. save settings). In addition the ESG-400 has a bipolar socket, two monopolar sockets, a neutral electrode socket, and a universal socket to connect applicators with instrument recognition. The power switch turns the generator on and off. Two contact quality indicators (one for split and one for non-split electrodes) are green illuminated if neutral electrodes are correctly connected. Three additional push buttons allow recalling a previously saved setting (Select Procedure), to assign the footswitches to specific output sockets (Footswitch), and to control several other functions (Menu), e.g. select language, touch tone control, output volume, or brightness.

On the rear panel the volume control, a ventilation hole, the equipotential bonding point, the AC power socket, and two footswitch sockets can be found. Furthermore, for the connection of peripheral equipment 26-pin plugs respectively 14-pin plugs can be connected to the LINK-IN or to the LINK-OUT socket.

On the bottom panel, a docking socket is featured. In future it might be used to connect the ESG-400 directly to upcoming devices.

Application Modes

Monopolar Cut:
- PureCut (Cutting of varying tissue structures; 3 Effects)
- BlendCut (Cutting of varying tissue structures; 3 Effects)
- PulseCut slow (Intermittent cutting; 3 Effects)

- PulseCut fast (Intermittent cutting; 3 Effects)

Monopolar Coagulation:
- SoftCoag (Coagulation of tissue with little sticking and carbonization; 3 Effects)
- ForcedCoag (Fast and effective coagulation; 3 Effects)
- SprayCoag (Contact-free surface coagulation with little penetration depth; 3 Effects)
- PowerCoag (Fast and effective coagulation with increased dissection capabilities; 3 Effects)

Bipolar Cut:
- BipolarCut (All bipolar cutting procedures of tissue structures; 3 Effects)
- SalineCut (Cutting in conductive fluid; 3 Effects; only available via UNIVERSAL socket)

Bipolar Coagulation:
- BiSoftCoag (Coagulation with little sticking and carbonization; 3 Effects)
- AutoCoag (Coagulation with little sticking and carbonization; 3 Effects)
- SalineCoag (Coagulation in conductive fluid; 3 Effects; only available via UNIVERSAL socket)
- HardCoag (Controlled tissue coagulation; 3 Effects)
- RFCoag (Controlled deep tissue coagulation; with and without RCAP)
- FineCoag (Coagulation of tissue with little sticking and carbonization; 1 Effect)

The modes have preset power levels that may be customized by the user in a defined range.

Design

The design of the ESG-400 complies with the following recognized consensus standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-4
- IEC 60601-1-8
- IEC 60601-2-2
- IEC 62304
- IEC 62366
- ISO 14971

Accessories

- Footswitch Double Pedal (WB50402W): It has a blue pedal that is used to activate the selected coagulation mode and a yellow pedal

that is used to activate the selected cutting mode.
- Footswitch Single Pedal (optional; WB50403W): It has a blue pedal that is used to activate the selected coagulation mode
- P-Cord (optional; MAJ-814): The P-cord is used to connect a patient plate to the ESG-400.

Intended Use:	The ESG-400 is an electrosurgical generator intended for cutting and coagulation of tissue in open, laparoscopic and endoscopic surgery in conjunction with electrosurgical accessories and ancillary equipment.
Comparison to Predicate Devices:	The ESG-400 has a similar indication statement as the predicate devices VIO 300 D and XUES-41. Furthermore, the subject ESG-400 has similar technological characteristics. There are differences in the output characteristics and the quantity of the application modes, the maximum output power, or the handling, but they do not change the safety and effectiveness or result in new potential risks. The data show that the differences between the subject ESG-400 and the predicate devices do not affect the safety and efficacy, as no changes were incorporated in the intended use, in the performance, and in the physical principles that the device is based upon. Therefore, no additional tests are necessary for evaluation of safety and efficacy. Nevertheless bench tests of the subject ESG-400 and the predicate devices VIO 300 D and XUES-41 were performed and demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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JAN 14 2011

Re: K103032
Trade/Device Name: ESG-400
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 06, 2011
Received: January 07, 2011

Dear Ms. Kluesner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103032

04 Indications for Use

510(k) Number (if known): K103032

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Device Name: *ESG-400*

Indications For Use:

The Olympus ESG-400 electrosurgical unit is intended for cutting and coagulation of tissue in open, laparoscopic and endoscopic surgery in conjunction with electrosurgical accessories and ancillary equipment.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103032